In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-917V

Filed: November 21, 2013

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EDWARD PRATT,	*	**TO BE PUBLISHED**
	*	
	*	Special Master
	*	Hamilton-Fieldman
Petitioner,	*	
	*	
v.	*	
	*	Decision on the Record, Dismissal of
SECRETARY OF HEALTH	*	Claim for Insufficient Proof; Failure to
AND HUMAN SERVICES,	*	Submit Expert Report; Influenza
	*	Vaccine, Guillain-Barrè syndrome.
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *		

Danielle Strait, Washington, DC, for Petitioner.
Lisa Watts, Washington, DC, for Respondent.

DISMISSAL DECISION[1]

On December 28, 2012, Edward Pratt ("Petitioner") filed a petition for Vaccine Compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] ("Program"). Petition ("Pet") at 1, ECF No. 1.

[1] Because this published decision contains a reasoned explanation for the action in the case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347 § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to file a motion for redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). In the absence of such motion, the entire decision will be available to the public. *Id.*

After a review of the petition and supporting documents, Petitioner's counsel filed a "Motion For A Decision On The Record," stating that Petitioner would not be proffering the opinion of a medical expert in support of vaccine causation of the injury alleged, and consequently, had elected not to pursue a formal causation hearing with expert witness testimony. Pet'r's Motion at 1, ECF No. 25.

I

PROCEDURAL HISTORY

On December 28, 2012, Petitioner filed a petition for vaccine compensation. Pet., ECF No. 1. The case was originally assigned to Chief Special Master Campbell-Smith. Notice, ECF No. 2. On January 4, 2013, Petitioner filed a "Motion For Subpoenae," seeking the authority to subpoena Johns Hopkins Hospital and the medical facility of Cardinal Hill. Motion, ECF No. 4. That Motion was granted on January 7, 2013.

The Chief Special Master issued an Initial Order in this case on January 8, 2013, stating that Petitioner should file a status report regarding the status of record collection by March 8, 2013. Order, ECF No. 6. This Order stated that when all records had been filed, Petitioner was to file a Statement of Completion, and Respondent was to file a Status Report regarding record review within 30 days of the filing of Petitioner's Statement of Completion, including a statement as to the expected filing date of Respondent's Rule 4(c) Report. *Id.*

Counsel for Respondent, Lisa Watts made an appearance on January 9, 2013. Notice, ECF No. 8. Additionally, on January 9, 2013, Petitioner filed Exhibits one through ten on compact disc.[3] Filing, ECF No. 7. On March 4, 2013, this case was reassigned to the undersigned pursuant to Vaccine Rule 3(d). Order, ECF No. 9.

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[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42. U.S.C. §300aa (2006).

[3] Submitted exhibits are labeled as follows: Exhibit 1-Vaccination Record, Exhibit 2- St. Mary's Hospital, Exhibit 3- Montgomery County Hospital, Exhibit 4-Physician's Now Urgent Care Center, Exhibit 5-Cabell Huntington Hospital Home Health, Exhibit 6-Huntington Physical Therapy, Exhibit 7-Gary Cremeans II, M.D., Exhibit 8-UK Medical Center, Exhibit 9-CMAC, Exhibit 10- Cornerstone Hospital of Huntington.

On March 8, 2013, Petitioner filed a Status Report regarding record collection, indicating that Petitioner had been collecting and reviewing medical records, and that Petitioner believed that outstanding records existed from one additional treating facility. Filing, ECF No. 10. On March 13, 2013, the undersigned issued a Scheduling Order, ordering Petitioner to file all medical records and a statement of completion on or before Tuesday May 7, 2013. Order, ECF No. 11.

On April 3, 2013, Petitioner filed Exhibits 11 and 12 on compact disc, designated as records from Cardinal Hill and Johns Hopkins Hospital. Notice, ECF No. 12. Petitioner filed his personal affidavit on April 3, 2013, designated as Exhibit 13. Filing, ECF No. 13. Petitioner filed a Statement of Completion on April 4, 2013. Statement, ECF No. 14.

The undersigned held a status conference on April 18, 2013, ordering Respondent's counsel to file a status report, indicating whether this case would be postured for settlement or litigation. Order, Apr. 25, 2013, ECF No. 15. Respondent's counsel filed a Rule 4(c) Report on May 23, 2013, accompanied by Exhibits A through C.[4] Respondent's counsel filed a Status Report on July 3, 2013, stating that "a settlement in this case w[ould] not be forthcoming." Status Report, ECF No. 20.

On October 9, 2013, Petitioner filed a Motion for Enlargement of Time to file a supportive medical expert report, and this Motion was granted the same day. Motion, ECF No. 23; Order, ECF No. 24. On November 8, 2013, Petitioner filed a Motion for Decision on the Record. Pet'r's Motion, ECF No. 25.

II

FACTUAL HISTORY

At the time of vaccination, Petitioner was 35 years old with a past medical history of hyperlipidemia (high levels of lipids or lipoproteins in the blood). Pet'r's Ex. 7 at 6. On October 7, 2011, Petitioner received a flu vaccine in his left deltoid. Pet'r's Ex. 1 at 1

Petitioner was seen at an urgent care center for chills/fever and diarrhea on December 13, 2011. Pet'r's Ex. 4 at 2-4. During this visit, it was noted under "history of present illness," that Petitioner had awakened with fever, sweats, and chills one week

[4] Exhibits accompanying Respondent's Report are as follows: Exhibit A-Vaccines and GBS, Exhibit B-Epidemiologic Evaluation of GBS and swine flu vaccine, Exhibit C-2011 IOM Published Excerpt flu vaccine and GBS.

ago. *Id.* at 2. Petitioner reported fatigue, difficulty sleeping, and reduced appetite. *Id.* Rapid tests for influenza A and B, infectious mononucleosis, and strep throat were all negative. *Id.* at 3. Petitioner's neurologic examination was within normal limits. *Id.* at 2. Diagnostic impressions were fever, fatigue/malaise, and diarrhea of presumed infectious origins. *Id.* at 3. He was prescribed Levaquin and advised to keep well-hydrated. *Id.*

On December 14, 2011, Petitioner was seen in the emergency room ("ER") at Montgomery General Hospital. Pet'r's Ex. 3 at 4-5. By history, it was noted that Petitioner had been "feeling sick for two weeks with n/v/d last week, and this week c/o chills, fevers, and sweats." *Id.* at 19. The previous day, he was seen in urgent care and prescribed Levaquin, but he only took one pill because after taking the medication he began sweating. *Id.* Petitioner woke up on the morning of admission with generalized weakness, greater in the lower extremities. *Id.* He reported driving to the ER and falling in the parking lot because his legs were weak. *Id.* at 4.

On examination at the ER, significant weakness was observed in Petitioner's lower extremities, and to a lesser extent, his upper extremities. Pet'r's Ex. 3 at 5. Sensation was intact. *Id.* Petitioner also had some right eye-lid lag and facial droop. *Id.* Possible Guillain-Barrè syndrome ("GBS") or other neurologic condition was suspected, and Petitioner was transferred to Johns Hopkins Hospital via helicopter under the care of Dr. Vinay Chaudhry, a neurologist. *Id.* at 5, 28, 34.

The admission assessment at Johns Hopkins noted that Petitioner had progressive bilateral lower extremity weakness "after a prolonged febrile & diarrheal illness." Pet'r's Ex. 9 at 743. He was seen by Dr. Chaudhry on December 15, 2011. Pet'r's Ex. 9 at 744-45. Again, it was recorded that Petitioner was "well until about 2 weeks ago when he had fever, chills, and myalgias. A week ago, this was followed by abdominal pain and diarrhea." *Id.* at 744. Two days ago, on December 13, 2011, Petitioner began noticing "unsteadiness" with walking, which progressed to the point where he could barely stand. *Id.* Neurologic exam revealed moderately severe weakness of the bilateral 7th nerve distribution in Petitioner's upper and lower face, severely reduced strength in his extremities, and absent reflexes in the lower extremities. *Id.* at 744-45. Under impression, Dr. Chaudhry's impression stated:

> This 35 year-old man, who is a construction worker and was in good health until a week ago when he had diarrhea followed by rapidly progressive weakness. The history and examination are highly consistent with Guillain-Barre syndrome. Campylobacter-induced GBS is likely in this setting.

Id. at 745. Dr. Chaudhry ordered a lumbar puncture and EMG, and Petitioner was admitted to the neurocritical care unit ("NCCU") for intravenous immunoglobulin treatment ("IVIG"). *Id.*

In the NCCU, Petitioner rapidly lost mobility of his upper and lower extremities. Pet'r's Ex. 9 at 720. His lumbar puncture on December 22, 2011, was abnormal, with a protein count of 205. *Id.* at 720. Results of Petitioner's Electromagnetic Nerve Conduction Studies ("EMG/NCS") showed a "conduction block with absent F waves." *Id.* Magnetic Resonance Imaging ("MRI") of the brain and cervical spine were normal. *Id.* Petitioner was intubated and required a tracheotomy and feeding tube. *Id.* IVIG treatment was completed on December 18, 2011, and a repeat EMG/NCS at that time showed greater axonal involvement. *Id.* Petitioner's discharge summary on January 2, 2012, again recorded a history of fever, chills, and generalized malaise two weeks prior to admission on December 14, 2011, followed by episodes of abdominal pain and diarrhea of four days duration. *Id.* at 719. Diagnoses were GBS and chronic back pain from a prior motor vehicle accident. *Id.* at 722, 755.

On June 2, 2012, Petitioner was initially admitted to inpatient rehabilitation at Charleston Area Medical Center ("CAMC"). Pet'r's Ex. 9 at 39. However, on January 10, 2012, he was admitted to the hospital with complaints of fever, tachycardia, and pleuritic chest pain. Pet'r's Ex. 9 at 2-5; 16-21. Petitioner's respiratory culture was positive for acinetobacter and pseudomonas. *Id.* at 3. A Computed Tomography ("CT") of Petitioner's chest revealed bilateral pulmonary embolism, and he was started on Levonox and Coumadin. *Id.* at 16-21. Petitioner continued to have severe weakness and burning pain in his extremities from his GBS, and received physical and occupational therapy throughout his hospitalization. *Id.* He was discharged from CAMC to Cornerstone Long-Term Acute Care Hospital ("Cornerstone") on January 25, 2012. *Id.*

Petitioner was hospitalized at Cornerstone from January 25, 2012, to February 16, 2012. Pet'r's Ex. 10 at 2-7. Tests for campylobacter jejuni antibody on January 27, 2012, were negative. *Id.* at 7.

Petitioner was admitted to Cardinal Hill Rehabilitation Hospital from February 17, 2012 to March 29, 2012. Pet'r's Ex. 5 at 23. It was noted that Petitioner was initially hospitalized on December 14, 2011, for progressive weakness after a short Gastrointestinal ("GI") illness in December. *Id.* at 29. On admission, Petitioner was too weak to use a manual wheelchair, and was dependent on others for all transfers and toileting. *Id.* at 35-39.

Petitioner's repeat EMG/NCS performed on April 23, 2012, showed "evidence of GBS axonal form with interval improvement," from the prior study on December 22, 2011. Pet'r's Ex. 8 at 6-7.

Petitioner was seen by his primary care physician on August 22, 2012, with continued diffuse global weakness due to GBS. Pet'r's Ex. 7 at 2. He had been in outpatient physical therapy ("PT") since April 2012, and was only recently able to raise his right arm above his head. *Id.* He could not raise his left arm above his head. *Id.* Petitioner was able to "take several steps" on a walker. *Id.* He recently had a CT of the chest which showed a residual clot in his lungs, so he was continued on Coumadin. *Id.* On examination, petitioner had "diffuse atrophies of most of the muscles of his body." *Id.*

III

DISCUSSION

To receive compensation under the Program, Petitioner must prove either 1) that he suffered a "Table Injury"- i.e., an injury falling within the Vaccine Injury Table- corresponding to one of his vaccinations, or 2) that he suffered an injury that was actually caused by a vaccine. *See* §300aa-13(a)(1)(A) and §300aa-11(c)(1).

Petitioner's petition alleged that he suffered from Guillain-Barrè syndrome as a result of receiving an influenza vaccination on October 7, 2011. Pet'r's Ex. 1 at 1.

To establish vaccine causation, Petitioner must satisfy all prongs of the test established by the court in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). To satisfy the first prong of the *Althen* test, Petitioner must provide "a medical theory causally connecting the vaccination and the injury." *Id.* (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir.1992)). Petitioner's theory must show that it is more likely than not that the vaccine Petitioner received can cause the injuries that Petitioner alleges the vaccine caused. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010).

To satisfy the second prong of the *Althen* test, Petitioner must establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. That is, Petitioner must show by preponderant evidence (more likely than not) that the vaccine he received *did* cause the injuries he alleges it caused. *See Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Finally, to satisfy the third prong of *Althen*, Petitioner must produce preponderant evidence of "a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. This prong helps to establish the connection between the causal theory of prong one and the more fact-based cause and effect arguments of prong two by demonstrating, "that the onset of symptoms occurred within a timeframe from which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

The undersigned is not authorized to make a finding of causation based on the claims of a Petitioner alone, unsubstantiated by medical records or a medical opinion. *See* 42 U.S.C. §300aa-13(a)(1). Petitioner stated he would not proffer an expert report in this case. A review of the record in this case provides no evidence demonstrating that Petitioner's medical condition was vaccine-caused.

Rather, the undersigned concurs with Dr. Chaudhry and finds that it is more likely than not that Petitioner's Guillain-Barrè syndrome was the result of the febrile and diarrheal illness he experienced one to two weeks prior to admission at Johns Hopkins Hospital . *See* Pet'r's Ex. 9 at 719, 741-745.

The temporal span between the administration of the influenza vaccine and the alleged onset of Petitioner's injury is too great to function as evidence of a causal association by a preponderance of the evidence. Petitioner received his influenza vaccination on October 7, 2011. Pet'r's Ex. 1 at 1. Alleged onset of Petitioner's Guillain-Barrè syndrome seems to have occurred around the time of December 14, 2011, when Petitioner began to experience generalized weakness in the lower extremities. Pet'r's Ex. 3 at 4-5. As such, onset of Petitioner's Guillain-Barrè syndrome occurred almost nine weeks after his influenza vaccination with the febrile and diarrheal illness occurring in the interim.

Without evidence of a reliable, scientific theory, a logical sequence of cause and effect, and a proximate temporal relationship between vaccination and alleged injury, Petitioner cannot meet his burden of proof under the three-prong test of *Althen*. The undersigned therefore **DENIES** Petitioner's claim.

IV

CONCLUSION

The undersigned is sympathetic to the fact that Petitioner suffers from a medical condition. However, under the law, the undersigned can authorize compensation only if a medical condition or injury either falls within one of the "Table Injury" categories, or is shown by medical records or a competent medical opinion to be vaccine-caused. No

such proof exists in this record. **Thus, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.**[5]

IT IS SO ORDERED.

/s/ Lisa Hamilton-Fieldman
Lisa Hamilton-Fieldman
Special Master

[5] To preserve whatever right Petitioners may have to file a civil action in another court, they must file an "Election to File a Civil Action" which rejects the judgment from this court within 90 days of the date judgment was filed.